

1AP20 Rec'd PCT/US 21 MAR 2006

## APPENDIX A

### FDA Approved Oncology Drugs

<u>Aldesteukin</u>	<u>Proleukin</u>		<u>Chiron Corp</u>	May 05 1992
<u>Alemtuzumab</u>	<u>Campath</u>	Accel. Approv. (clinical benefit not established) Campath is indicated for the treatment of B-cell chronic lymphocytic leukemia (B-CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy.	<u>Millennium and ILEX Partners, I.P</u>	May 07 2001
<u>altretinoin</u>	<u>Panretin</u>	Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.	<u>Ligand Pharmaceuticals</u>	Feb 02 1999
<u>allopurinol</u>	<u>Zyloprim</u>	Patients with leukemia, lymphoma and solid tumor malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels and who cannot tolerate oral therapy.	<u>GlaxoSmithKline</u>	May 17 1996
<u>altretamine</u>	<u>Hexalen</u>	Single agent palliative treatment of patients with persistent or recurrent ovarian cancer following first-line therapy with a cisplatin and/or alkylating agent based combination.	<u>US Bioscience</u>	Dec 26 1990
<u>amifostine</u>	<u>Ethyol</u>	To reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer	<u>US Bioscience</u>	Dec 08 1995
<u>amifostine</u>	<u>Ethyol</u>	Accel. Approv. (clinical benefit not established) Reduction of platinum toxicity in non-small cell lung cancer	<u>US Bioscience</u>	Mar 15 1996
<u>amifostine</u>	<u>Ethyol</u>	To reduce post-radiation xerostomia for head and neck cancer where the radiation port includes a substantial portion of the parotid glands.	<u>US Bioscience</u>	Jun 24 1999
<u>anastrozole</u>	<u>Arimidex</u>	Accel. Approv. (clinical benefit not established) for the adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer	<u>AstraZeneca</u>	Sep 05 2002
<u>anastrozole</u>	<u>Arimidex</u>	Treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy.	<u>AstraZeneca Pharmaceuticals</u>	Dec 27 1995
<u>anastrozole</u>	<u>Arimidex</u>	For first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer.	<u>AstraZeneca Pharmaceuticals</u>	Sep 01 2000
<u>arsenic trioxide</u>	<u>Trisenox</u>	Second line treatment of relapsed or refractory APL following ATRA plus an anthracycline.	<u>Cell Therapeutic</u>	Sep 25 2000
<u>Asparaginase</u>	<u>Elspar</u>	ELSPAR is indicated in the therapy of patients with acute lymphocytic leukemia. This agent is useful primarily in combination with other chemotherapeutic agents in the induction of remissions of the disease in pediatric patients.	<u>Merck &amp; Co. Inc</u>	Aug 01 2002
<u>BCG Live</u>	<u>TICE BCG</u>		<u>Organon Teknica Co</u>	Aug 21 1998
<u>bevacizumab</u>	<u>Targretin</u>	For the treatment by oral capsule of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.	<u>Ligand Pharmaceuticals</u>	Dec 29 1999
<u>bevacizumab</u>	<u>Tarotin</u>	For the topical treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.	<u>Ligand Pharmaceuticals</u>	Jun 28 2000
<u>bleomycin</u>	<u>Blenoxane</u>		<u>Bristol-Myers Squibb</u>	Jul 31 1973
<u>bleomycin</u>	<u>Blenoxane</u>	Sclerosing agent for the treatment of malignant pleural effusion (MPE) and prevention of recurrent pleural effusions.	<u>Bristol-Myers Squibb</u>	Feb 20 1996
<u>busulfan intravenous</u>	<u>Busulfex</u>	Use in combination with cyclophosphamide as conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia.	<u>Orphan Medical, Inc</u>	Feb 04 1999
<u>busulfan oral</u>	<u>Myleran</u>	Chronic Myelogenous Leukemia- palliative therapy	<u>GlaxoSmithKline</u>	Jun 26 1954
<u>calusterone</u>	<u>Methosarb</u>		<u>Pharmacia &amp; Upjohn Company</u>	Feb 20 1973
<u>capecitabine</u>	<u>Xeloda</u>	Accel. Approv. (clinical benefit subsequently established) Treatment of metastatic breast cancer resistant to both paclitaxel and an anthracycline containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy may be contraindicated, e.g., patients who have received cumulative doses of 400 mg/m <sup>2</sup> of doxorubicin or doxorubicin equivalents	<u>Roche</u>	Apr 30 1998
<u>capecitabine</u>	<u>Xeloda</u>	Initial therapy of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred. Combination chemotherapy has shown a survival benefit compared to 5-FU/LV alone. A survival benefit over 5-FU/LV has not been demonstrated with Xeloda monotherapy.	<u>Roche</u>	Apr 30 2001
<u>capecitabine</u>	<u>Xeloda</u>	Treatment in combination with docetaxel of patients with metastatic breast cancer after failure of prior anthracycline containing chemotherapy	<u>Roche</u>	Sep 07 2001
<u>carboplatin</u>	<u>Pareplatin</u>	Palliative treatment of patients with ovarian carcinoma recurrent after prior chemotherapy, including patients who have been previously treated with cisplatin.	<u>Bristol-Myers Squibb</u>	Mar 03

				1989
<u>carboplatin</u>	<u>Paraplatin</u>	Initial chemotherapy of advanced ovarian carcinoma in combination with other approved chemotherapeutic agents.	<u>Bristol-Myers Squibb</u>	Jul 05 1991
<u>camustine</u>	<u>BCNU, BiCNU</u>		<u>Bristol-Myers Squibb</u>	Mar 07 1977
<u>carmustine with Polifeprosan 20 Implant</u>	<u>Gliadel Wafer</u>	For use in addition to surgery to prolong survival in patients with recurrent glioblastoma multiforme who qualify for surgery.	<u>Gilford Pharmaceuticals Inc.</u>	Sep 23 1996
<u>cetuximab</u>	<u>Celebrex</u>	Accel. Approv. (clinical benefit not established) Reduction of polyp number in patients with the rare genetic disorder of familial adenomatous polyposis.	<u>Searle</u>	Dec 23 1999
<u>chlorambucil</u>	<u>Leukeran</u>	Chronic Lymphocytic Leukemia- palliative therapy	<u>GlaxoSmithKline</u>	
<u>chlorambucil</u>	<u>Leukeran</u>		<u>GlaxoSmithKline</u>	Mar 18 1957
<u>cisplatin</u>	<u>Platinol</u>	Metastatic testicular-in established combination therapy with other approved chemotherapeutic agents in patients with metastatic testicular tumors who have already received appropriate surgical and/or radiotherapeutic procedures. An established combination therapy consists of Platinol, Bleomycin and Vinblastine.	<u>Bristol-Myers Squibb</u>	Dec 19 1978
<u>cisplatin</u>	<u>Platinol</u>	Metastatic ovarian tumors - in established combination therapy with other approved chemotherapeutic agents: Ovarian-in established combination therapy with other approved chemotherapeutic agents in patients with metastatic ovarian tumors who have already received appropriate surgical and/or radiotherapeutic procedures. An established combination consists of Platinol and Adriamycin. Platinol, as a single agent, is indicated as secondary therapy in patients with metastatic ovarian tumors refractory to standard chemotherapy who have not previously received Platinol therapy.	<u>Bristol-Myers Squibb</u>	Dec 19 1978
<u>cisplatin</u>	<u>Platinol</u>	as a single agent for patients with transitional cell bladder cancer which is no longer amenable to local treatments such as surgery and/or radiotherapy.	<u>Bristol-Myers Squibb</u>	Apr 22 1993
<u>cladribine</u>	<u>Leustatin, 2-CdA</u>	Treatment of active hairy cell leukemia.	<u>R.W. Johnson Pharmaceutical Research Institute</u>	Feb 26 1993
<u>cyclophosphamide</u>	<u>Cytoxan, Neosar</u>		<u>Bristol-Myers Squibb</u>	Nov 16 1959
<u>cyclophosphamide</u>	<u>Cytoxan Injection</u>		<u>Bristol-Myers Squibb</u>	Nov 16 1959
<u>cyclophosphamide</u>	<u>Cytoxan Injection</u>		<u>Bristol-Myers Squibb</u>	Apr 29 1987
<u>cyclophosphamide</u>	<u>Cytoxan Tablet</u>		<u>Bristol-Myers Squibb</u>	Apr 29 1987
<u>cytarabine</u>	<u>Cytosar-U</u>		<u>Pharmacia &amp; Upjohn Company</u>	Jun 17 1969
<u>cytarabine liposomal</u>	<u>DepoCyt</u>	Accel. Approv. (clinical benefit not established) Intrathecal therapy of lymphomatous meningitis	<u>Skye Pharmaceuticals</u>	Apr 01 1999
<u>dacarbazine</u>	<u>DTC-Dome</u>		<u>Bayer</u>	May 27 1975
<u>dactinomycin, actinomycin D</u>	<u>Cosmegen</u>		<u>Merck</u>	Feb 04 1964
<u>dactinomycin, actinomycin D</u>	<u>Cosmegen</u>		<u>Merck</u>	Dec 10 1964
<u>Darbepoetin alfa</u>	<u>Aranesp</u>	Treatment of anemia associated with chronic renal failure.	<u>Amgen, Inc</u>	Sep 17 2001
<u>Darbepoetin alfa</u>	<u>Aranesp</u>	Aranesp is indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.	<u>Amgen, Inc</u>	Jul 19 2002
<u>daunorubicin liposomal</u>	<u>DauvoXome</u>	First line cytotoxic therapy for advanced, HIV related Kaposi's sarcoma.	<u>Nexstar, Inc.</u>	Apr 08 1996
<u>daunorubicin, daunomycin</u>	<u>Daunorubicin</u>	Leukemia/myelogenous/monocytic/erythroid of adults/remission induction in acute lymphocytic leukemia of children and adults.	<u>Bedford Labs</u>	Jan 30 1998
<u>daunorubicin, daunomycin</u>	<u>Cerubidine</u>	In combination with approved anticancer drugs for induction of remission in adult ALL.	<u>Wyeth-Ayerst</u>	Mar 11 1987

Denileukin diftitox	Ontak	Accel. Approv. (clinical benefit not established) treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor	Seragen, Inc	Feb 05 1999
dexrazoxane	Zinecard	Accel. Approv. (clinical benefit subsequently established) Prevention of cardiomyopathy associated with doxorubicin administration	Pharmacia & Upjohn Company	May 26 1995
dexrazoxane	Zinecard	reducing the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m <sup>2</sup> and who will continue to receive doxorubicin therapy to maintain tumor control. It is not recommended for use with the initiation of doxorubicin therapy.	Pharmacia & Upjohn Company	Oct 31 2002
docetaxel	Taxotere	Accel. Approv. (clinical benefit subsequently established) Treatment of patients with locally advanced or metastatic breast cancer who have progressed during anthracycline-based therapy or have relapsed during anthracycline-based adjuvant therapy.	Aventis Pharmaceutical	May 14 1996
docetaxel	Taxotere	For the treatment of locally advanced or metastatic breast cancer which has progressed during anthracycline-based treatment or relapsed during anthracycline-based adjuvant therapy.	Aventis Pharmaceutical	Jun 22 1998
docetaxel	Taxotere	For locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy.	Aventis Pharmaceutical	Dec 23 1999
docetaxel	Taxotere		Aventis Pharmaceutical	Nov 27 2002
docetaxel	Taxotere	in combination with cisplatin for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer who have not previously received chemotherapy for this condition.	Aventis Pharmaceutical	Nov 27 2002
doxorubicin	Adriamycin Rubex		Pharmacia & Upjohn Company	Aug 07 1974
doxorubicin	Adriamycin PES Injection/intravenous injection	Antibiotic, antitumor agent.	Pharmacia & Upjohn Company	Dec 23 1987
doxorubicin liposomal	Doxil	Accel. Approv. (clinical benefit not established) Treatment of AIDS-related Kaposi's sarcoma in patients with disease that has progressed on prior combination chemotherapy or in patients who are intolerant to such therapy.	Sequus Pharmaceuticals, Inc.	Nov 17 1995
doxorubicin liposomal	Doxil	Accel. Approv. (clinical benefit not established) Treatment of metastatic carcinoma of the ovary in patient with disease that is refractory to both paclitaxel and platinum based regimens	Sequus Pharmaceuticals, Inc.	Jun 28 1999
DROMOSTANOLONE PROPIONATE	DROMOSTANOLONE		Eli Lilly	Oct 26 1961
DROMOSTANOLONE PROPIONATE	MASTERONE INJECTION		SYNTEX	Oct 08 1964
Elliott's B Solution	Elliott's B Solution	Diluent for the intrathecal administration of methotrexate sodium and cytarabine for the prevention or treatment of meningeal leukemia or lymphocytic lymphoma.	Orphan Medical, Inc	Sep 27 1996
epirubicin	Ellence	A component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.	Pharmacia & Upjohn Company	Sep 15 1999
Epoetin alfa	epogen	EPOGENB is indicated for the treatment of anemia related to therapy with zidovudine in HIV-infected patients. EPOGENB is indicated to elevate or maintain the red blood cell level (as manifested by the hematocrit or hemoglobin determinations) and to decrease the need for transfusions in these patients. EPOGEND is not indicated for the treatment of anemia in HIV-infected patients due to other factors such as iron or folate deficiencies, hemolysis or gastrointestinal bleeding, which should be managed appropriately.	Amgen, Inc	Jul 26 1999
Epoetin alfa	epogen	EPOGENB is indicated for the treatment of anemic patients (hemoglobin > 10 to < 13 g/dL) scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions.	Amgen, Inc	Jul 26 1999
Epoetin alfa	epogen	EPOGENB is indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy. EPOGEND is indicated to decrease the need for transfusions in patients who will be receiving concomitant chemotherapy for a minimum of 2 months. EPOGENB is not indicated for the treatment of anemia in cancer patients due to other factors such as iron or folate deficiencies, hemolysis or gastrointestinal bleeding, which should be managed appropriately.	Amgen, Inc	Jul 26 1999
Epoetin alfa	epogen	EPOGEN is indicated for the treatment of anemia associated with CRF, including patients on dialysis (ESRD) and patients not on dialysis.	Amgen, Inc	Jul 26 1999
estramustine	Emcyt	palliation of prostate cancer	Pharmacia & Upjohn Company	Dec 24 1981
etoposide phosphate	Etopophos	Management of refractory testicular tumors. In combination with other approved chemotherapeutic agents.	Bristol-Myers Squibb	May 17 1996
		Management of small cell lung cancer, first-line, In combination with other approved		May

<u>etoposide phosphate</u>	<u>Etopophos</u>	chemotherapeutic agents.	<u>Bristol-Myers Squibb</u>	17 1998
<u>etoposide phosphate</u>	<u>Etopophos</u>	Management of refractory testicular tumors and small cell lung cancer.	<u>Bristol-Myers Squibb</u>	Feb 27 1998
<u>etoposide, VP-16</u>	<u>Vepesid</u>	Refractory testicular tumors-in combination therapy with other approved chemotherapeutic agents in patients with refractory testicular tumors who have already received appropriate surgical, chemotherapeutic and radiotherapeutic therapy.	<u>Bristol-Myers Squibb</u>	Nov 10 1983
<u>etoposide, VP-16</u>	<u>VePesid</u>	In combination with other approved chemotherapeutic agents as first line treatment in patients with small cell lung cancer.	<u>Bristol-Myers Squibb</u>	Dec 30 1986
<u>etoposide, VP-16</u>	<u>Vepesid</u>	In combination with other approved chemotherapeutic agents as first line treatment in patients with small cell lung cancer.	<u>Bristol-Myers Squibb</u>	Dec 30 1986
<u>exemestane</u>	<u>Aromasin</u>	Treatment of advance breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.	<u>Pharmacia &amp; Upjohn Company</u>	Oct 21 1999
<u>Filgrastim</u>	<u>Neupogen</u>		<u>Amgen, Inc</u>	Feb 20 1991
<u>Filgrastim</u>	<u>Neupogen</u>	NEUPOGEN is indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, eg, febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation.	<u>Amgen, Inc</u>	Apr 02 1998
<u>Filgrastim</u>	<u>Neupogen</u>	NEUPOGEN is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever.	<u>Amgen, Inc</u>	Apr 02 1998
<u>Filgrastim</u>	<u>Neupogen</u>	NEUPOGEN is indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.	<u>Amgen, Inc</u>	Apr 02 1998
<u>flouxuridine (intraarterial)</u>	<u>FUDR</u>		<u>Roche</u>	Dec 18 1970
<u>fludarabine</u>	<u>Fludara</u>	Palliative treatment of patients with B-cell lymphocytic leukemia (CLL) who have not responded or have progressed during treatment with at least one standard alkylating agent-containing regimen.	<u>Berlex Laboratories Inc.</u>	Apr 18 1991
<u>fluorouracil, 5-FU</u>	<u>Adrucil</u>	prolong survival in combination with leucovorin	<u>ICN Puerto Rico</u>	Apr 25 1962
<u>fulvestrant</u>	<u>Faslodex</u>	the treatment of hormone receptor-positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy	<u>IPR</u>	Apr 25 2002
<u>gemcitabine</u>	<u>Gemzar</u>	Treatment of patients with locally advanced (nonresectable stage II or III) or metastatic (stage IV) adenocarcinoma of the pancreas. Indicated for first-line treatment and for patients previously treated with a 5-fluorouracil-containing regimen.	<u>Eli Lilly</u>	May 15 1996
<u>gemcitabine</u>	<u>Gemzar</u>	For use in combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer.	<u>Eli Lilly</u>	Aug 25 1998
<u>gemtuzumab ozogemtuzumab</u>	<u>Mylotarg</u>	Accel. Approv. (clinical benefit not established) Treatment of CD33 positive acute myeloid leukemia in patients in first relapse who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy.	<u>Wyeth Ayerst</u>	May 17 2000
<u>goserelin acetate</u>	<u>Zoladex Implant</u>	Palliative treatment of advanced breast cancer in pre- and perimenopausal women.	<u>AstraZeneca Pharmaceuticals</u>	Dec 18 1995
<u>goserelin acetate</u>	<u>Zoladex</u>		<u>AstraZeneca Pharmaceuticals</u>	Dec 18 1995
<u>hydroxyurea</u>	<u>Hydrea</u>		<u>Bristol-Myers Squibb</u>	Dec 07 1967
<u>hydroxyurea</u>	<u>Hydrea</u>	Decrease need for transfusions in sickle cell anemia	<u>Bristol-Myers Squibb</u>	Feb 25 1998
<u>Ibrutinomab Tiuxetan</u>	<u>Zevalin</u>	Accel. Approv. (clinical benefit not established) treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma, including patients with Rituximab refractory follicular non-Hodgkin's lymphoma.	<u>IDEC Pharmaceuticals Corp</u>	Feb 19 2002
<u>idarubicin</u>	<u>Idamycin</u>	For use in combination with other approved antileukemic drugs for the treatment of acute myeloid leukemia (AML) in adults.	<u>Adria Laboratories</u>	Sep 27 1990
<u>idarubicin</u>	<u>Idamycin</u>	In combination with other approved antileukemic drugs for the treatment of acute non-lymphocytic leukemia in adults.	<u>Pharmacia &amp; Upjohn Company</u>	Feb 17 1997
<u>ifosfamide</u>	<u>IFEX</u>	Third line chemotherapy of germ cell testicular cancer when used in combination with certain other approved antineoplastic agents.	<u>Bristol-Myers Squibb</u>	Dec 30 1988

<u>imatinib mesylate</u>	<u>Gleevec</u>	Accel. Approv. (clinical benefit not established) Initial therapy of chronic myelogenous leukemia	<u>Novartis</u>	May 10 2001
<u>imatinib mesylate</u>	<u>Gleevec</u>	Accel. Approv. (clinical benefit not established) metastatic or unresectable malignant gastrointestinal stromal tumors	<u>Novartis</u>	Feb 01 2002
<u>imatinib mesylate</u>	<u>Gleevec</u>	Accel. Approv. (clinical benefit not established) Initial treatment of newly diagnosed Ph+ chronic myelogenous leukemia (CML).	<u>Novartis</u>	Dec 20 2002
<u>Interferon alfa-2a</u>	<u>Roferon-A</u>		<u>Hoffmann-La Roche Inc</u>	Nov 01 1996
<u>Interferon alfa-2b</u>	<u>Intron A</u>	Interferon alfa-2b, recombinant for injection is indicated as adjuvant to surgical treatment in patients 18 years of age or older with malignant melanoma who are free of disease but at high risk for systemic recurrence within 56 days of surgery.	<u>Schering Corp</u>	Nov 06 1997
<u>Interferon alfa-2b</u>	<u>Intron A</u>	Interferon alfa-2b, recombinant for injection is indicated for the initial treatment of clinically aggressive follicular Non-Hodgkin's Lymphoma in conjunction with anthracycline-containing combination chemotherapy in patients 18 years of age or older.	<u>Schering Corp</u>	Nov 06 1997
<u>Interferon alfa-2b</u>	<u>Intron A</u>	Interferon alfa-2b, recombinant for injection is indicated for intralesional treatment of selected patients 18 years of age or older with condylomata acuminata involving external surfaces of the genital and perianal areas.	<u>Schering Corp</u>	Nov 06 1997
<u>Interferon alfa-2b</u>	<u>Intron A</u>	Interferon alfa-2b, recombinant for injection is indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease who have a history of blood or blood-product exposure and/or are HCV antibody positive.	<u>Schering Corp</u>	Nov 06 1997
<u>Interferon alfa-2b</u>	<u>Intron A</u>	Interferon alfa-2b, recombinant for injection is indicated for the treatment of chronic hepatitis B in patients 18 years of age or older with compensated liver disease and HBV replication.	<u>Schering Corp</u>	Nov 06 1997
<u>Interferon alfa-2b</u>	<u>Intron A</u>	Interferon alfa-2b, recombinant for injection is indicated for the treatment of patients 18 years of age or older with hairy cell leukemia.	<u>Schering Corp</u>	Nov 06 1997
<u>Interferon alfa-2b</u>	<u>Intron A</u>	Interferon alfa-2b, recombinant for injection is indicated for the treatment of selected patients 18 years of age or older with AIDS-Related Kaposi's Sarcoma. The likelihood of response to INTRON A therapy is greater in patients who are without systemic symptoms, who have limited lymphadenopathy and who have a relatively intact immune system as indicated by total CD4 count.	<u>Schering Corp</u>	Nov 06 1997
<u>Interferon alfa-2b</u>	<u>Intron A</u>		<u>Schering Corp</u>	Jun 21 2002
<u>Interferon alfa-2b</u>	<u>Intron A</u>		<u>Schering Corp</u>	Jun 21 2002
<u>Interferon alfa-2b</u>	<u>Intron A Intron A</u>		<u>Schering Corp</u>	Jun 21 2002
<u>irinotecan</u>	<u>Camptosar</u>	Accel. Approv. (clinical benefit subsequently established) Treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5-FU-based therapy.	<u>Pharmacia &amp; Upjohn Company</u>	Jun 14 1996
<u>irinotecan</u>	<u>Camptosar</u>	Follow up of treatment of metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5-FU-based therapy.	<u>Pharmacia &amp; Upjohn Company</u>	Oct 22 1998
<u>irinotecan</u>	<u>Camptosar</u>	For first line treatment in combination with 5-FU/leucovorin of metastatic carcinoma of the colon or rectum.	<u>Pharmacia &amp; Upjohn Company</u>	Apr 20 2000
<u>letrozole</u>	<u>Femara</u>	Treatment of advanced breast cancer in postmenopausal women.	<u>Novartis</u>	Jul 25 1997
<u>letrozole</u>	<u>Femara</u>	First-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer.	<u>Novartis</u>	Jan 10 2001
<u>letrozole</u>	<u>Femara</u>		<u>Novartis</u>	Jan 17 2003
<u>leucovorin</u>	<u>Wellcovorin, Leucovorin</u>	Leucovorin calcium is indicated for use in combination with 5-fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer.	<u>Immunex Corporation</u>	Jun 20 1982
<u>leucovorin</u>	<u>Leucovorin</u>		<u>Immunex Corporation</u>	Jan 30 1987
<u>leucovorin</u>	<u>Leucovorin</u>		<u>Immunex Corporation</u>	Jan 30 1987
<u>leucovorin</u>	<u>Leucovorin</u>		<u>Immunex Corporation</u>	Aug 31 1988
<u>leucovorin</u>	<u>Leucovorin</u>	In combination with fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer.	<u>Lederle Laboratories</u>	Dec 12

levamisole	Ergamisol	Adjuvant treatment in combination with 5-fluorouracil after surgical resection in patients with Dukes' Stage C colon cancer.	Janssen Research Foundation	Jun 18 1990
lomustine, CCNU	CeeBU		Bristol-Myers Squibb	Aug 04 1978
mechlorethamine, nitrogen mustard	Mustargen		Merck	Mar 15 1949
megestrol acetate	Megace		Bristol-Myers Squibb	Aug 18 1971
meiphalan, I-PAM	Alkeran		GlaxoSmithKline	Jan 17 1964
meiphalan, I-PAM	Alkeran	Systemic administration for palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.	GlaxoSmithKline	Nov 18 1992
mercaptopurine, 6-MP	Purinethol		GlaxoSmithKline	Sep 11 1953
mesna	Mesnex	Prevention of ifosfamide-induced hemorrhagic cystitis	Asta Medica	Dec 30 1988
methotrexate	Methotrexate		Lederle Laboratories	Dec 07 1953
methotrexate	Methotrexate		Lederle Laboratories	Aug 10 1959
methotrexate	Methotrexate		Lederle Laboratories	Nov 01 1971
methotrexate	Methotrexate		Lederle Laboratories	Nov 01 1971
methotrexate	Methotrexate	osteosarcoma	Lederle Laboratories	Apr 07 1968
methotrexate	Methotrexate		Lederle Laboratories	Oct 31 1988
methoxsalen	Uvadex	For the use of UVADEX with the UVAR Photopheresis System in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.	Therakos	Feb 25 1999
mitomycin C	Mutamycin		Bristol-Myers Squibb	May 28 1974
mitomycin C	Mitozytrex	therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed.	Supergen	Nov 14 2002
mitotane	Lysodren		Bristol-Myers Squibb	Jul 08 1970
mitoxantrone	Noventrone	For use in combination with corticosteroids as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer.	Immunex Corporation	Nov 13 1996
mitoxantrone	Noventrone	For use with other approved drugs in the initial therapy for acute nonlymphocytic leukemia (ANLL) in adults.	Lederle Laboratories	Dec 23 1987
nandrolone phenpropionate	Durabolin-50		Organon	Oct 30 1959
Nofelumomab	Verluma		Boehringer Ingelheim Pharma KG (formerly Dr. Karl Thomae GmbH)	Aug 20 1996
Oprelvekin	Neumega		Genetics Institute, Inc	Nov 25 1997
Oprelvekin	Neumega		Genetics Institute, Inc	Sep 18 2002
Oprelvekin	Neumega	Neumega is indicated for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive chemotherapy in adult patients with nonmyeloid malignancies who are at high risk of	Genetics Institute, Inc	Sep 18 2002

<u>oxaliplatin</u>	<u>Eloxatin</u>	severe thrombocytopenia.		
<u>paclitaxel</u>	<u>Paxene</u>	treatment of advanced AIDS-related Kaposi's sarcoma after failure of first line or subsequent systemic chemotherapy	<u>Baker Norton Pharmaceuticals, Inc</u>	Dec 24 1997
<u>paclitaxel</u>	<u>Taxol</u>	Treatment of patients with metastatic carcinoma of the ovary after failure of first-line or subsequent chemotherapy.	<u>Bristol-Myers Squibb</u>	Dec 29 1992
<u>paclitaxel</u>	<u>Taxol</u>	Treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.	<u>Bristol-Myers Squibb</u>	Apr 13 1994
<u>paclitaxel</u>	<u>Taxol</u>	New dosing regimen for patients who have failed initial or subsequent chemotherapy for metastatic carcinoma of the ovary	<u>Bristol-Myers Squibb</u>	Jun 22 1994
<u>paclitaxel</u>	<u>Taxol</u>	second line therapy for AIDS related Kaposi's sarcoma.	<u>Bristol-Myers Squibb</u>	Aug 04 1997
<u>paclitaxel</u>	<u>Taxol</u>	For first-line therapy for the treatment of advanced carcinoma of the ovary in combination with cisplatin.	<u>Bristol-Myers Squibb</u>	Apr 09 1998
<u>paclitaxel</u>	<u>Taxol</u>	for use in combination with cisplatin, for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.	<u>Bristol-Myers Squibb</u>	Jun 30 1998
<u>paclitaxel</u>	<u>Taxol</u>	For the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination therapy.	<u>Bristol-Myers Squibb</u>	Oct 25 1999
<u>paclitaxel</u>	<u>Taxol</u>	First line ovarian cancer with 3 hour infusion.	<u>Bristol-Myers Squibb</u>	Jun 20 2000
<u>pamidronate</u>	<u>Aredia</u>	Treatment of osteolytic bone metastases of breast cancer in conjunction with standard antinaoplastic therapy.	<u>Novartis</u>	Sep 22 1998
<u>pegademase</u>	<u>Adagen (Pegademase Bovine)</u>	Enzyme replacement therapy for patients with severe combined immunodeficiency asa result of adenosine deaminase deficiency.	<u>Enzon</u>	Mar 21 1990
<u>Pegasparagase</u>	<u>Oncaspar</u>		<u>Enzon, Inc</u>	Feb 01 1994
<u>Pegfilgrastim</u>	<u>Neulasta</u>	Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.	<u>Amgen, Inc</u>	Jan 31 2002
<u>pentostatin</u>	<u>Nipent</u>	Single agent treatment for adult patients with alpha interferon refractory hairy cell leukemia.	<u>Parke-Davis Pharmaceutical Co.</u>	Oct 11 1991
<u>pentostatin</u>	<u>Nipent</u>	Single-agent treatment for untreated hairy cell leukemia patients with active disease as defined by clinically significant anemia, neutropenia, thrombocytopenia, or disease-related symptoms. (Supplement for front -line therapy.)	<u>Parke-Davis Pharmaceutical Co.</u>	Sep 29 1993
<u>pipobroman</u>	<u>Vercyte</u>		<u>Abbott Labs</u>	Jul 01 1966
<u>placamycin, mitramycin</u>	<u>Mithracin</u>		<u>Pfizer Labs</u>	May 05 1970
<u>porfimer_sodium</u>	<u>Photofrin</u>	For use in photodynamic therapy (PDT) for palliation of patients with completely obstructing esophageal cancer, or patients with partially obstructing esophageal cancer who cannot be satisfactorily treated with ND-YAG laser therapy.	<u>QLT Phototherapeutics Inc.</u>	Dec 27 1995
<u>porfimer_sodium</u>	<u>Photofrin</u>	For use in photodynamic therapy for treatment of microinvasive endobronchial nonsmall cell lung cancer in patients for whom surgery and radiotherapy are not indicated.	<u>QLT Phototherapeutics Inc.</u>	Jan 09 1998
<u>porfimer_sodium</u>	<u>Photofrin</u>	For use in photodynamic therapy (PDT) for reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial nonsmall cell lung cancer (NSCLC).	<u>QLT Phototherapeutics Inc.</u>	Dec 22 1998
<u>procabazine</u>	<u>Matulane</u>		<u>Sigma Tau Pharms</u>	Jul 22 1969
<u>quinacrine</u>	<u>Atabrine</u>		<u>Abbott Labs</u>	Dec 07 1964
<u>Rasburicase</u>	<u>Elitek</u>	ELITEK is indicated for the initial management of plasma uric acid levels in pediatric patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anti-cancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid.	<u>Sanofi-Synthelabo, Inc</u>	Jul 12 2002

Rituximab	Rituxan		Genentech, Inc	Nov 26 1997
Sargramostim	Prokine		Immunex Corp.	Nov 07 1995
streptozocin	Zanosar	Antineoplastic agent.	Pharmacia & Upjohn Company	May 07 1982
talc	Sclerosol	For the prevention of the recurrence of malignant pleural effusion in symptomatic patients.	Bryon	Dec 24 1997
tamoxifen	Nolvadex		AstraZeneca Pharmaceuticals	Dec 30 1977
tamoxifen	Nolvadex	As a single agent to delay breast cancer recurrence following total mastectomy and axillary dissection in postmenopausal women with breast cancer (T1-3, N1, M0)	AstraZeneca Pharmaceuticals	Dec 03 1986
tamoxifen	Nolvadex	For use in premenopausal women with metastatic breast cancer as an alternative to oophorectomy or ovarian irradiation	AstraZeneca Pharmaceuticals	Mar 16 1989
tamoxifen	Nolvadex	For use in women with axillary node-negative breast cancer adjuvant therapy.	AstraZeneca Pharmaceuticals	Jun 21 1990
tamoxifen	Nolvadex	Metastatic breast cancer in men.	AstraZeneca Pharmaceuticals	Apr 01 1993
tamoxifen	Nolvadex	Equal bioavailability of a 20 mg Nolvadex tablet taken once a day to a 10 mg Nolvadex tablet taken twice a day.	AstraZeneca Pharmaceuticals	Mar 21 1994
tamoxifen	Nolvadex	to reduce the incidence of breast cancer in women at high risk for breast cancer	AstraZeneca Pharmaceuticals	Oct 29 1998
tamoxifen	Nolvadex	In women with DCIS, following breast surgery and radiation, Nolvadex is indicated to reduce the risk of invasive breast cancer.	AstraZeneca Pharmaceuticals	Jun 29 2000
temozolamide	Temozol	Accel. Approv. (clinical benefit not established) Treatment of adult patients with refractory anaplastic astrocytoma, i.e., patients at first relapse with disease progression on a nitrosourea and procarbazine containing regimen	Schering	Aug 11 1999
teniposide, VM-26	Vumon	In combination with other approved anticancer agents for induction therapy in patients with refractory childhood acute lymphoblastic leukemia (all).	Bristol-Myers Squibb	Jul 14 1992
testolactone	Testolac		Bristol-Myers Squibb	Jun 03 1969
testolactone	Testolac		Bristol-Myers Squibb	May 27 1970
thioguanine, 6-TG	Thioguanine		GlaxoSmithKline	Jan 18 1965
thioplepa	Thioplex		Immunex Corporation	Mar 09 1959
thioplepa	Thioplex		Immunex Corporation	Dec 22 1994
thioplepa	Thioplex		Lederm Laboratories	Aug 15 1990
topotecan	Hycamtin	Treatment of patients with metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy.	GlaxoSmithKline	May 28 1995
topotecan	Hycamtin	Treatment of small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the phase 3 study) or at least 90 days (in the phase 2 studies) after chemotherapy	GlaxoSmithKline	Nov 30 1998
toremifene	Fareston	Treatment of advanced breast cancer in postmenopausal women.	Orion Corp.	May 29 1997
Tositumomab	Bexxar	Accel. Approv. (clinical benefit not established) Treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma, with and without transformation, whose disease is refractory to Rituximab and has relapsed following chemotherapy	Corixa Corporation	Jun 27 2003
Trastuzumab	Hercaptin	HERCEPTIN as a single agent is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have received one or more chemotherapy regimens for their metastatic disease.	Genentech, Inc	Sep 25 1998

Trastuzumab	Herceptin	Herceptin in combination with paclitaxel is indicated for treatment of patients with metastatic breast cancer whose tumors overexpress the HER-2 protein and had not received chemotherapy for their metastatic disease	Genentech, Inc	Feb 09 2000
Trastuzumab	Herceptin		Genentech, Inc	Dec 11 2001
Trastuzumab	Herceptin		Genentech, Inc	Aug 28 2002
Trastuzumab	Herceptin		Genentech, Inc	Aug 28 2002
tretinoin, ATRA	Vesanoid	Induction of remission in patients with acute promyelocytic leukemia (APL) who are refractory to or unable to tolerate anthracycline based cytotoxic chemotherapeutic regimens.	Roche	Nov 22 1995
Uracil Mustard	Uracil Mustard Capsules		Roberts Labs	Sep 13 1962
valrubicin	Velstar	For intravesical therapy of BCG-refractory carcinoma in situ (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.	Anthra -> Medeva	Sep 25 1998
vinblastine	Velban		Eli Lilly	Nov 05 1965
vincristine	Oncovin		Eli Lilly	Jul 10 1963
vincristine	Oncovin		Eli Lilly	Jul 10 1963
vincristine	Oncovin		Eli Lilly	Jul 10 1963
vincristine	Oncovin		Eli Lilly	Jul 10 1963
vincristine	Oncovin		Eli Lilly	Jul 10 1963
vincristine	Oncovin		Eli Lilly	Jul 10 1963
vinorelbine	Navelbine	Single agent or in combination with cisplatin for the first-line treatment of ambulatory patients with unresectable, advanced non-small cell lung cancer (NSCLC).	Glaxo SmithKline	Dec 23 1994
vinorelbine	Navelbine	Navelbine is indicated as a single agent or in combination with cisplatin for the first-line treatment of ambulatory patients with unresectable, advanced non-small cell lung cancer (NSCLC). In patients with Stage IV NSCLC, Navelbine is indicated as a single agent or in combination with cisplatin. In Stage III NSCLC, Navelbine is indicated in combination with cisplatin.	Glaxo SmithKline	Nov 05 2002
zoledronate	Zometa	the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy	Novartis	Feb 22 2002